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Copy of Response

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Prof. Richard C. Willson III
and Jason Murphy
Serial No.: 10/737,403

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) Filed: 16 Dec. 2003
) Examiner Samuel C.
) Woolwine

For: ... **INTRODUCTION OF STRUCTURAL
AFFINITY HANDLES AS A TOOL IN
SELECTIVE NUCLEIC ACID SEPARATIONS**

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Priority: 12 July 1999, Provis. 60/143, 768
Attorney Docket: ..009AUS

) Art Unit 1637

Response Due: 8 February 2007

RESPONSE TO REQUIREMENT OF ELECTION

*** Assistant Commissioner for Patents

Box US; Group 1743
Washington, DC 20231

Sir:

In respect to the Office Action mailed 8 January 2007, consideration of the
following remarks is requested.

The undersigned Attorney certifies that this Document has
been filed in the U.S. Patent and Trademark Office via fax to
1571 273 8300 addressed as above on 18 January 2007 (37
CFR 1.10).

The Invention

This invention embodies processes and compositions formed in the course of a
rapid, scaleable, nuclease-free (preferably RNase free), cost effective method of
nucleic acid purification comprising introduction of affinity handles into the

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desired (or undesired) product, and use of those handles to separate out the moiety having handles.

The Requirement

For reference, pages 2 and following of the Office Action are set below with responses interlineated:

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DETAILED ACTION

Election/Restrictions

Claim 1 is generic to the following disclosed patentably distinct species: single stranded regions of nucleic acids, triplexes, hairpins, stems, loops, cruciforms, quartets, and modifications to the phosphate backbone, all of which are disclosed by Applicant as "affinity handles" (see claim 2). The species are independent or distinct because each of these "affinity handles" represents a unique structure with unique properties. The use of one such structure as an "affinity handle" would not render obvious the use of the others as "affinity handles" a priori.

In addition a search of the method with respect to each of the recited "affinity handles" would impose a serious burden on the examiner. There is no reason to expect that a search for the use of one type of structure as an "affinity handle" would result in prior art disclosing the other structures as affinity handles, and so a separate search would be required for each of the recited structures.

Claim 4 is generic to the following disclosed patentably distinct species: immobilized metal affinity chromatography, immobilized single-stranded DNA binding (SSB) protein, immobilized nucleic acids, and the use of peptide nucleic acids, all of which are disclosed by Applicant as "separation steps" (see claim 6). The species are independent or distinct because each of these "separation steps" represents a distinct mechanism of interaction between distinct pairs of binding partners. The use of one [Page 3] such "separation step" for separation of nucleic acids would not render the use of the others as obvious a priori.

In addition a search of the method with respect to each of the recited "separation steps" would impose a serious burden on the examiner. There is no reason to expect that a search for the use of one type of separation step for the separation of nucleic acids would result in prior art disclosing the other separation steps, and so a separate search would be required for each of the separation steps.

Claim 1 is generic to the following disclosed patentably distinct species: selective thermal denaturation and renaturation, alkaline denaturation, the use of chaotropic agents, the use of restriction enzymes yielding single-stranded overhangs, the use of oligonucleotide dTs, single-stranded DNA binding proteins, minerals, and the use of primers or other nucleic acid fragments such as complementary DNA nucleic acids, all of which are disclosed by Applicant as "steps for introducing handles" (see claim 10). The species are independent or distinct because each of these steps represents a distinct means for introducing handles. The use of one such means would not render the use of the others as obvious a priori.

In addition a search of the method with respect to each of the recited means for introducing handles would impose a serious burden on the examiner. There is no reason to expect that a search for one of the recited means in the context of introducing affinity handles would result in prior art disclosing the other recited means, and so a separate search would be required for each of the recited members.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of [Page 5] record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner wishes to stress that this is a requirement for an election of species only. If a generic claim becomes allowable, or if during the search of the prior art it becomes clear that the recited species are not patentably distinct, the requirement for election of species will be withdrawn. Therefore, Applicant is advised that there is no need to cancel claims at this time based on the requirement for an election of species.

Furthermore, the examiner has indicated on the summary page for this Office action that claims 1-25 are pending, even though there are markings on the scanned image of the claims in the file which seem to indicate a desire to cancel claims 20-24 and re-number claim 25 as claim 20. Applicant is required in response to this Office action to clarify for the record which claims are pending. If claims 20-24 are to be cancelled, this should be clearly stated in the response, and claim 25 should remain numbered as claim 25. This application has been published on July 20, 2006 as US20060160093 A1 with claims 1-25. Therefore, this numbering should be preserved throughout the course of prosecution. [Page 6]

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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